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10/543,022	09/14/2006	Niva Shapira	32467	4059

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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,022	SHAPIRA ET AL.	
	Examiner	Art Unit	
	AUDREA BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,63-66,68-70,74,75 and 77-87* is/are pending in the application.

4a) Of the above claim(s) *69,70 and 82-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,63-66,68,74,75 and 77-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This action is in response to remarks and amendments filed 3/16/2011. Claims 1, 63-66, 68-70, 74, 75, and 77-87 are pending. Claims 69, 70, and 82-87 remain withdrawn. Examined claims which were amended include claims 1, 68, 74, 77, and 78. No new claims were added. Claims 1, 63-66, 68, 74, 75, and 77-81 are under current examination.

Withdrawn Claim Rejections

The rejection of claims 1, 63-66, 68, 74, 75, and 77-81 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of Applicant's amendments to the claims filed 3/16/2011.

The rejection of claims 1, 63-66, 68, 74, and 77-81 under 35 U.S.C. 103(a) as being unpatentable over Lambert (US 6,284,265 B1) as evidenced by Handelman and further in view of Grimberg is withdrawn in light of Applicants' amendments to the claims filed 3/16/2011.

The rejection of claim 75 under 35 U.S.C. 103(a) as being unpatentable over Lambert (US 6,284,265 B1) as evidenced by Handelman and further in view of Grimberg and further in view of Howard et al. is withdrawn in light of Applicants' amendments to the claims filed 3/16/2011.

Response to Arguments

Applicant's arguments presented 3/16/2011 have been fully considered but are not persuasive in light of amendment. As noted above, all rejections previously presented and not re-iterated herein are withdrawn in light of the amendments to the

claims. Regarding the rejection under 35 U.S.C. 112, second paragraph, the previous rejection is withdrawn because Applicant's amendment corrects the previous antecedent basis problem. Regarding the prior art rejections, specifically, since claim 1 now recites the limitation "at least one antacid" instead of "at least one antacid component", the Lambert reference as the primary reference has been withdrawn in order to address the narrowed scope of the claims.

It is noted that in the remarks filed 3/16/2011, Applicant presents additional arguments against the secondary Howard reference, however these arguments pertain to the combination of the Howard reference with the Lambert reference. The relevance of the Howard reference is maintained as set forth below, however the combination of Howard and Lambert has been withdrawn on account of the amendments to the claims, therefore these arguments are moot.

New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 63, 64, 68, 74, 77, and 79-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Dixon (US 6,372,264 B1, issued Apr. 16, 2002).

Regarding claims 1, 68, 74, and 77, Dixon teaches a compounded coordination complex of calcium that balances ionic calcium and does not contribute to unbalanced calcium metabolism, cellular malfunction, or calcified arterial plaque buildup (see abstract, in particular). In Example 1, Dixon discloses a method for preparing this composition. Five-hundred milligrams of calcium carbonate complex (antacid) was dissolved in 100 mL distilled water (pharmaceutically acceptable carrier as defined on page 27, line 30 of the instant specification), and 1000 mg ascorbic acid (antioxidant), of vegetable source (plant derived antioxidant), was added. This composition comprises 67% w/w of the total antacid and antioxidant mass. As to claim 80, this composition is a liquid. Since the calcium carbonate complex is complexed with amino acids, and since Dixon teaches the complex agent as one which is capable of binding the cationic component with the ascorbic acid component, a binder is included in the formulation (see column 6, lines 1-4). The composition was heated and further isolated according to Dixon's procedure, and the formulations were known to be suitable for oral administration (see column 6, line 42).

The language "for potentiating antioxidative activities" recites an intended use which does not materially limit the structure of the claimed composition. See MPEP 2111.02 regarding claim interpretation of intended use recitations in product claims. Likewise, the language "in a dose capable of elevating the pH in a stomach by at least one pH unit" pertains to a process for using the claimed composition, because the circumstances by which a stomach pH may be elevated depend on the particular stomach and circumstances to which the antacid is administered. For instance, a

stomach with a starting pH of 1.5 will not necessarily be increased by a unit of one upon administration of the same "dose" of antacid administered to a stomach with a starting pH of 3.5. Since product-by-process claims are not limited to the manipulations of the recited steps, but rather are limited by the structure of the claim, this language does not appear to alter the structure of the claimed composition in a limiting way.

As to the limitations of claims 63 and 64, the claimed functionality would have been inherent to the formulation disclosed by Dixon since each and every structural limitation of pending claim 1 was present in the formulation of Dixon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 63, 64, 68, 74, and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon (US 6,372,264 B1, issued Apr. 16, 2002).

Regarding claims 1, 68, 74, and 77, Dixon teaches a compounded coordination complex of calcium that balances ionic calcium and does not contribute to unbalanced calcium metabolism, cellular malfunction, or calcified arterial plaque buildup (see abstract, in particular; see also, column 12, lines 22-29). In Example 1, Dixon discloses a method for preparing this composition. Five-hundred milligrams of calcium carbonate complex (antacid) was dissolved in 100 mL distilled water (pharmaceutically acceptable carrier as defined on page 27, line 30 of the instant specification), and 1000 mg ascorbic acid (antioxidant), of vegetable source (plant derived antioxidant), was added. This composition comprises 67% w/w of the total antacid and antioxidant mass. As to claim 80, this composition is a liquid. Since the calcium carbonate complex is complexed with amino acids, and since Dixon teaches the complex agent as one which is capable of binding the cationic component with the ascorbic acid component, a binder is included in the formulation (see column 6, lines 1-4). The composition was heated

and further isolated according to Dixon's procedure, and the formulations were known to be suitable for oral administration (see column 6, line 42).

The language "for potentiating antioxidative activities" recites an intended use which does not materially limit the structure of the claimed composition. See MPEP 2111.02 regarding claim interpretation of intended use recitations in product claims. Likewise, the language "in a dose capable of elevating the pH in a stomach by at least one pH unit" pertains to a process for using the claimed composition, because the circumstances by which a stomach pH may be elevated depend on the particular stomach and circumstances to which the antacid is administered. For instance, a stomach with a starting pH of 1.5 will not necessarily be increased by a unit of one upon administration of the same "dose" of antacid administered to a stomach with a starting pH of 3.5. Since product-by-process claims are not limited to the manipulations of the recited steps, but rather are limited by the structure of the claim, this language does not appear to alter the structure of the claimed composition in a limiting way. As to the limitations of claims 63 and 64, the claimed functionality would have been inherent to the formulation disclosed by Dixon since each and every structural limitation of pending claim 1 was present in the formulation of Dixon.

Regarding claims 1, 63, 64, 68, 74, 77, and 79-81, it is established that when a reference anticipates an invention, it necessarily renders such invention obvious as well. *Anticipation is the "epitome of Obviousness", In re Kalm*, 378 F.2d 959, 962 (CCPA 1967).

As to claim 78, the Dixon reference does not teach the instantly recited antioxidant quantity being limited to a value between 40 and 60% of the total antacid and antioxidant "weight" as instantly recited. However, Dixon does teach that the particular ratio of ingredients is not intended to limit the invention such that the ordinary artisan would have been able to, for example, decrease the presence of antioxidant by approximately ten percent relative to the above-cited Example 1 and to still reasonably expect success from this modification of the disclosed embodiment. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform routine optimization procedures and to adjust the formulation components in accordance with the teaching of Dixon, with a reasonable expectation of success. One would have been motivated to do so because it is routine in the art to optimize formulation component ratios in order to maximize benefits and minimize negative side effects.

Claims 65 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon (US 6,372,264 B1, issued Apr. 16, 2002) as applied to claims 1, 63, 64, 68, 74, and 77-81 above and further in view of Howard et al. (US 6,099,854, issued Aug. 8, 2000, previously cited).

The teachings of Dixon are delineated above. Regarding claims 65 and 75, Dixon does not teach a second distinct antioxidant or the particular instantly recited polyphenols.

Howard et al. teaches food supplement compositions containing flavonol. The flavonol is derived from wine and includes polyphenols. The formulations of Howard et al. include medicaments for human consumption for inhibition of platelet aggregation (see column 4, lines 1-22; column 12, lines 65-67).

Both Dixon and Howard are directed to compositions for preventing arterial plaque build-up. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the polyphenols as taught by Dixon to the formulations of Howard, with a reasonable expectation of success particularly since Howard teaches that the compositions may comprise any number of further components such as those typically used in the pharmaceutical industry (see column 8, lines 12-15). One would have been motivated to do so since Howard teaches that oral consumption of the composition desirably inhibits oxidation of plasma LDL and inhibits platelet aggregation (see column 9, lines 11-27). It is noted that upon this combination of teachings, the formulation would have comprised two distinct antioxidants as required by claim 65.

Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon (US 6,372,264 B1, issued Apr. 16, 2002) as applied to claims 1, 63, 64, 68, 74, and 77-81 above and further in view of Day et al. (US 4,824,672, issued Apr. 25, 1989).

The teachings of Dixon are delineated above. Regarding claim 66, Dixon does not teach at least a second distinct antacid.

However, Day et al. teach orally administrable compositions for reducing serum cholesterol levels in which a mineral salt is included (see abstract, in particular). Day teaches calcium carbonate and magnesium carbonate to be equivalent mineral salts which may be employed (see column 1, lines 7-15; column 6, lines 42-43).

Both Dixon and Day are directed to formulations for cholesterol reduction and subsequently the minimizing arterial plaque. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the calcium carbonate active of Dixon with the equivalent magnesium carbonate as taught by Day, with a reasonable expectation of success. MPEP 2144.06 states that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.3d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One would have been motivated to do so in order to form a third composition useful for the very same purpose of minimizing arterial plaque upon oral administration of the formulation.

Conclusion

No claims are found allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635